Amendment 1
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on behalf of the ECR Group

Report **A7-0027/2013**
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Protection of public health from endocrine disrupters
2012/2066(INI)

Motion for a resolution (Rule 157(4) of the Rules of Procedure) replacing non-legislative motion for a resolution A7-0027/2013

European Parliament resolution on the protection of public health from endocrine disrupters

The European Parliament,

– having regard to Regulation (EC) No 1907/2006[1] of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC(7) ('the REACH Regulation'),

– having regard to Regulation (EC) No 1272/2008[2] of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 199/45/EC, and amending Regulation (EC) No 1907/2006,

– having regard to Regulation (EC) No 1107/2009[3] of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC,

– having regard to Regulation (EU) No 528/2012[4] of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products,

– having regard to Directive 2000/60/EC[5] of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ('the WFD'),

[1] OJ L 36, 5.2.2009, p. 84.
[2] OJ L 353, 31.12.08, p.1.
[3] OJ L 309, 24.11.09, p.1.
[4] OJ L 167, 27.6.2012, p. 1.
[5] OJ L 327, 22.12.2000, p.1.

– having regard to Directive No 2009/128/EC[1] of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides,

– having regard to Regulation (EC) No 1223/2009[2] of the European Parliament and of the Council of 30 November 2009 on cosmetic products,

– having regard to the Commission proposal for a directive of the European Parliament and of the Council amending Directives 2000/60/EC and 2008/105/EC as regard priority substances in the field of water policy,

– having regard to the OECD conceptual framework for testing and assessment of endocrine disrupters,

– having regard to the draft guidance document on standardised test guidelines for evaluating chemicals for endocrine disruptions (2011).

– having regard to the draft detailed review paper entitled 'State of the sciences on novel in vitro and in vivo screening and testing methods and endpoints for evaluating endocrine disruptors',

– having regard to the upcoming Commission proposal on a 'Blueprint to safeguard Europe's water resources',

– having regard to the Commission Staff working paper on 'The implementation of the 'Community Strategy for Endocrine Disrupters' – a range of substances suspected of interfering with the hormone systems of humans and wildlife' (COM(1999)0706), (COM (2001)0262 and (SEC(2004)1372),

– having regard to the Commission Staff working paper '4th Report on the implementation of the 'Community Strategy for Endocrine Disrupters' – a range of substances suspected of interfering with the hormone systems of humans and wildlife' (COM (1999)0706), (SEC(2011)1001),

– having regard to the European Environment and Health Strategy and the EU Action Plan on Environment and Health (2004-2010), which, inter alia, recognise a need to take into account combined exposure of chemicals in risk assessments,

– having regard to the Commission's communication to the Council on the precautionary principle (COM(2000)0001),

– having regard to EEA Technical Report No 2/2012 'The impacts of endocrine disrupters on wildlife, people and their environments',

– having regard to its report of 20 October 1998 on endocrine-disrupting chemicals[3],

[1] OJ L 309, 24.11.2009, p. 71.
[2] OJ L 342, 22.12.2009, p. 59.
[3] Texts adopted, P4_TA(1998)0608.

– having regard to its report of 6 May 2010 on the Commission communication entitled 'Action against cancer: European partnership'[1],

– having regard to its report of 20 April 2012 on the review of the 6th Environment Action Programme and the setting of priorities for the 7th Environment Action Programme – A better environment for a better life[2],

– having regard to the 'Study on the scientific evaluation of 12 substances in the context of the endocrine disrupter priority list of actions',

– having regard to the Study of DHI Water and Environment on enhancing the endocrine disrupter priority list with a focus on low-production-volume chemicals,

– having regard to the 'State-of-the-art assessment of endocrine disrupters', Project Contract Number 070307/2009/550687/SER/D3,

– having regard to 'The impacts of endocrine disrupters on wildlife, people and their environments', the Weybridge+15 (1996–2011) report (ISSN 1725-2237),

– having regard to Directive (EU) No 2010/63 of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

– having regard to the definition for endocrine disrupting chemicals developed by the World Health Organisation (WHO) and the International Programme on Chemical Safety (IPCS)[3];

– having regard to Rule 48 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0027/2013),

A. whereas hormone-related disorders and illnesses in humans have increased over the last 20 years, including impaired sperm quality, early onset of puberty, increased incidence of deformed sexual organs, increased incidence of certain forms of cancer , and metabolic diseases; whereas certain neurological disorders and neurodegenerative diseases, impacts on neurodevelopmental functions, the immune system or epigenetics, might be linked to exposure to chemical substances with endocrine-disrupting properties; whereas further research is needed to obtain a better understanding of the causes of such diseases;

B. whereas chemical substances acting as endocrine disrupters can have oestrogenic or anti-oestrogenic effects which interfere with the function of the female reproductive system, altering hormone concentrations and menstrual cycles of women, as well as their fertility,

[1] OJ C 81 E, 15.3.2011, p. 95.
[2] Texts adopted, P7_TA(2012)0147.
[3] Definition from the WHO/IPCS (2002) report: 'An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.' A potential endocrine disruptor is 'an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations.' (http://www.who.int/ipcs/publications/en/ch1.pdf)

favouring the development of uterine diseases, such as fibroids and endometriosis, and affecting breast growth and lactation; whereas such substances have been identified as risk factors responsible for premature puberty in girls, breast cancer, miscarriage and impaired fertility or infertility;

C. whereas an increasing number of scientific studies have suggested that endocrine disrupting chemicals, particularly in combination, play a role in both chronic diseases, including hormone related cancers, obesity, diabetes, cardiovascular disease and also in reproductive problems;

D. whereas there is now significant scientific evidence that hormone-related disorders in wildlife – including reproductive abnormalities, the masculinisation of gastropods, the feminisation of fish or the decline of many mollusc populations in various parts of the world – are linked to the impact of chemicals with endocrine-disrupting properties;

E. whereas there are many possible causes for the growing frequency of hormone-related disorders in humans; whereas there is now significant scientific evidence that this is partly due to the impact of chemicals with endocrine-disrupting properties;

F. whereas there are major difficulties in proving the causal link between exposure to individual chemicals and disruption of the hormonal balance with risk of health impacts;

G. whereas, in the case of chemicals with endocrine-disrupting properties, the difficulties of proving a causal link are exacerbated by a number of factors, such as that:

– a long time may elapse between exposure and the epigenetic effects, and endocrine disrupters can have a detrimental effect several generations into the future;

– the risk of a negative impact varies in magnitude at different stages of development, and critical windows, e.g. during foetal development, may be very short;

– during their lives, people are exposed to a large number of chemicals in complex mixtures;

– endocrine disrupters can interact with each other and with the body's own endocrine system;

– endocrine disrupters can act at extremely low concentrations and thus cause adverse effects at a low dosage; where the dose-response relationship is non-monotonic, the difficulty of prediction increases still further;

– our knowledge of human and animal endocrine systems is still limited;

H. whereas EU legislation contains legal provisions concerning endocrine disrupters, but lacks criteria for determining whether a substance should be regarded as having endocrine-disrupting properties, which undermines proper application of the legal provisions; whereas a timetable should be set up to ensure the swift application of the future criteria;

I. whereas, at EU level, there are no coordinated or combined monitoring programmes

specifically dedicated to endocrine disrupters;

J. whereas there is little if any co-ordination regarding the way that data are collected, managed, assessed and reported across the different monitoring programmes;

K. whereas, as things stand at present, it is not legally possible to consider combination effects between endocrine disrupters released by products governed by different sets of regulations;

L. whereas the standard data requirements in EU chemicals legislation are insufficient to identify endocrine-disrupting properties in an adequate manner;

M. Whereas a number of EU laws are aimed at protecting citizens from exposure to harmful chemicals; whereas current EU legislation, however, assesses each exposure individually and does not provide for a comprehensive, integrated assessment of cumulative effects that takes into account different routes of exposure or different product types;

1. Considers, on the basis of an overall assessment of the state of knowledge, that the precautionary principle, in accordance with Article 192 (2) of the Treaty on the Functioning of the EU (TFEU), requires the Commission and the legislators to take adequate measures to reduce short- and long-term exposure of humans to endocrine disrupters where necessary, while undertaking a much greater research effort to improve the state of the scientific knowledge on the impact of endocrine disrupters on human health;

2. Points out that the precautionary principle applies in a world of scientific uncertainty, in which a risk can be characterised only on the basis of imperfect knowledge – neither set in stone nor beyond challenge – but in which it is necessary to act in order to avert or reduce potentially serious or irreversible consequences for human health and/or the environment;

3. Takes the view that where adverse effects of endocrine disrupting substances can reasonably be presumed, measures to protect human health have to be implemented; stresses, moreover, given the potential of endocrine disrupting substances to cause harmful or irreversible effects, that the absence of precise knowledge, including final proof of causal links, should not prevent health protection measures to be taken in line with the precautionary principle, keeping in mind the principle of proportionality;

4. Considers that protecting women from potential risks of endocrine disrupters for their reproductive health is of utmost importance; calls, therefore, on the Commission to prioritise research funding to study the effects of hormone disrupters on women's health, and to support long-term studies monitoring women's health over large spans of their lives, thus allowing an evidence-based assessment of the long-term and multi-generational effects of exposure to endocrine disrupters;

5. Calls, therefore, on the Commission to submit, as soon as possible, proposals for overarching criteria based on the definition of endocrine disrupters prepared by the World Health Organisation's International Programme on Chemical Safety (WHO/IPCS), together with testing and information requirements for chemicals on the commercial market, and for EU legislation to make clear what is regarded as a substance with

endocrine-disrupting properties; advocates considering the introduction of 'endocrine disrupter' as a regulatory class, with different categories based on the strength of evidence;

6. Stresses that it is essential to base the criteria for determining endocrine disrupting properties on a comprehensive hazard assessment carried out on the basis of state-of-the-art science, taking into account potential combination effects as well as long-term effects and effects during critical windows of development; the hazard assessment should then be utilized in the risk assessment and risk management procedures as prescribed in various relevant legislation;

7. Calls on the Commission to take further action in the field of chemicals policy and step up research that provides both for the assessment of the endocrine disrupting potential of individual chemicals as well as the possibility to assess the cumulative impact of identified combinations of substances on the endocrine system;

8. Takes the view that the criteria for defining endocrine disrupters should be based on criteria for defining 'adverse effect' and 'endocrine mode of action'; the WHO/IPCS definition being the appropriate basis for that purpose; considers that both 'adverse effect' and 'endocrine mode of action' must be examined and weighed up in parallel in a comprehensive assessment; considers that observed effects should be assumed to be harmful if there is scientific data to indicate this; stresses that any possible combination effects, such as mixtures or cocktail effects, should be taken into consideration;

9. Stresses that the criteria determining what constitutes an endocrine disrupter must be scientifically based and horizontal; considers that a weight-of-evidence approach should be used and that no single criterion should be seen as cut-off or decisive for the identification of an endocrine disrupter; considers that a socio-economic assessment should then be carried out in accordance with the relevant legislation;

10. Takes the view that all peer-reviewed scientific data and information, including a review of the scientific literature and non-GLP studies, should be taken into account, subject to their strengths and weaknesses, in assessing whether a substance does or does not have endocrine-disrupting properties; further considers it important to take account of modern methods and up-to-date research;

11. Calls on the Commission to introduce in all relevant EU legislation appropriate testing requirements for the identification of substances with endocrine-disrupting properties; considers that the most recently validated and internationally recognised testing methods – such as those developed by the OECD, the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) or the US Environmental protection Agency (EPA) Endocrine Disruptor Screening Program – must be implemented; notes that the OECD programme of testing methods covers sex hormones and thyroid hormones as well as steroidogenesis; points out, on the other hand, that there are no tests for many other areas of the endocrine system, e.g. insulin and growth hormones; considers that testing methods and guidance documents should be developed so as to take better account of endocrine disrupters, possible low-dose effects, combination effects and non-monotonic dose-response relationships, in particular with regard to critical windows of exposure during development;

12. The development of non-animal test methods should be promoted in order to produce safety data relevant to humans and to replace animal studies currently in use;

13. Believes that the use of non-animal test methods and other risk assessment strategies should be promoted, and that animal testing should be minimised and tests on vertebrates should be undertaken as a last resort; recalls that, in accordance with Directive 2010/63/EU, tests on vertebrate animals must be replaced, restricted or refined; calls, therefore, on the Commission to lay down rules to avoid duplicative testing and to ensure that duplication of tests and studies on vertebrates is prohibited;

14. Invites the Commission and the Member States to develop registers of reproductive health disorders to fill the existing data gap at EU level;

15. Invites the Commission and the Member States to develop reliable data on the socio-economic impacts of hormone-related disorders and illnesses;

16. Considers that it should be possible for decision-making bodies to deal with substances having the same modes of action and properties on a group basis when sufficient data is available, while in the absence of sufficient data it may be useful to group substances on the basis of structural similarity, for example in order to establish priorities for further testing, in order to protect the public as quickly and effectively as possible from the effects of exposure to endocrine disrupters, and limiting the number of animal tests; takes the view that grouping chemicals with structural similarity should be applied if the manufacturer or importer is unable to demonstrate the safety of a chemical to the satisfaction of the relevant decision making bodies; points out that, in such cases, these bodies may use information from chemicals of similar structure to complement the available data on a given chemical that is being considered by the bodies in order to reach conclusions regarding which subsequent steps need to be taken;

17. Calls on the Commission to revise its EU strategy on endocrine disrupters so that it delivers effective protection of human health by placing greater emphasis on the precautionary principle, while observing the proportionality principle, to work towards reducing human exposure to endocrine disrupters where necessary;

18. Urges the Commission and the Member States to take greater account of the fact that consumers need to have reliable information – presented in an appropriate form and in a language that they can understand – about the dangers of endocrine disrupters, their effects, and possible ways of protecting themselves;

19. Calls on the Commission to put forward a concrete timetable for applying the future criteria and modified testing requirements for endocrine disrupters in relevant legislation, including reviews of the approval of active substances used in pesticides and biocides, and a roadmap with specific actions and targets to reduce exposure to endocrine disrupters;

20. Considers that the database on hormonally active substances, developed as part of the current strategy, should be continually updated;

21. Calls on the Commission, as part of its current review of the 1999 Community strategy on endocrine disrupters, to carry out a systematic examination of all relevant current

legislation and, where necessary no later than 1st of June 2015, to amend existing legislation or to come forward with new legislative proposals, including hazard and risk assessments, so as to reduce the exposure of humans – in particular vulnerable groups such as pregnant women, babies, children and teenagers – to hormone disrupters as appropriate;

22. Calls on the Commission, when carrying out its future review of EU strategy on endocrine disrupters, to lay down an exact timetable, specifying the intermediate stages, for the purposes of:

    – applying the future criteria serving to identify possible endocrine-disrupting chemicals;

    – reviewing the relevant legislation referred to in paragraph 22;

    – publishing a regularly updated list of priority endocrine disrupters, the first version of which should be published by 20 December 2014;

    – taking all measures necessary to reduce the exposure of the EU public and the environment to endocrine disrupters;

23. Takes the view that endocrine disrupters should be regarded as Substances of Very High Concern within the meaning of the Reach Regulation, or the equivalent under other legislation;;

24. Stresses that current science does not give sufficient grounds for setting a limit value for certain substances below which adverse effects do not occur and that certain endocrine disruptors should therefore be regarded as 'non-threshold' substances. insists therefore that the manufacturer of a substance should prove that a limit value below which adverse effects do not occur can be identified. Where a threshold cannot be identified, appropriate measures should be taken according to the provisions of the relevant legislation;

25. Calls on the Commission to support targeted research projects on substances likely to affect the endocrine system and to emphasise the adverse effects at low concentrations or through combined exposure, including the development of new testing and analysis methods, as well as supporting a new paradigm shift based on pathways of toxicity/adverse outcome pathways; calls on the Commission to incorporate endocrine disrupters, their combination effects, and related subjects in the priorities for the research and development framework programme;

26. Calls on the Commission to develop in vitro and in silico methods in order to minimise animal testing for endocrine disrupters screening;

27. Calls on the Commission to require all products imported from third countries to comply with all present and future EU legislation on endocrine disrupters;

28. Calls on the Commission to include all relevant stakeholders in cooperation efforts to introduce the necessary legislative changes, in order to improve protection of human health from hormone-disrupting chemicals, and to devise information campaigns;

29. Calls on the Commission to consider the possibility of establishing a research centre for endocrine disrupters which should research in and coordinate knowledge on endocrine disrupters at EU level;

30. Calls on the Commission to ensure that all relevant current and future legislation applies horizontally the criteria for identifying known, probable and potential endocrine disrupters, so as to achieve a high level of protection;

31. Stresses that while this resolution is limited to addressing the protection of human health from endocrine disrupters, it is equally important to take decisive action to protect wildlife and the environment from endocrine disrupters;

32. Urges the Commission to promote and finance public information programmes on the health risks of endocrine disrupters, so as to allow consumers, in full knowledge of the facts, to adapt their behaviour and lifestyles; these information programmes should, in particular, focus on the most vulnerable groups (pregnant women and children), so that precautionary measures can be taken in good time;

33. Calls on the Member States to improve training programmes for health professionals in this field;

34. Welcomes the inclusion of endocrine disrupting chemicals (EDCs) among the emerging policy issues managed under the Strategic Approach to International Chemicals Management (SAICM) policy framework; calls on the Commission and the Member States to support these SAICM activities, and to promote active policies to reduce human and environment exposure to EDCs in all relevant international forums, including the WHO) and the United Nations Environment Programme (UNEP);

35. Instructs its President to forward this resolution to the Council and the Commission.

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